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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,334	06/19/2001	Sylvain Chemtob	2861-4003	9475

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MORGAN & FINNEGAN, L.L.P.
345 PARK AVENUE
NEW YORK, NY 10154

EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	13

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/787,334	CHEMTOB ET AL.	
	Examin r	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *6 and 7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Amendment A, filed 2/27/03, has been entered into the record. Claims 1-9 were pending in the application and claims 1-5 and 8-9 were the subject of the Office Action dated 11/29/02. In Amendment A Applicants cancelled claims 8 and 9. therefore, claims 1-7 are pending and claims 1-5 are the subject of this Office Action.

B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

A. The objection to the title has been withdrawn in view of Applicants' amendments.

B. The specification remains objected to since, though Applicants have amended the first line of the specification to recite the priority information, it is not clear if PCT/CA99/00844 is a CON, DIV, or CIP of U.S. Application No. 09/154,627.

C. The objection to Figure 2a has been withdrawn since Applicants removed the term PCP-8 from the Brief Description of the Figures.

3. Claim Objections

A. All claim objections have been withdrawn in view of Applicants' amendments or cancellation of the claims. However, a new objection appears below.

B. Claims 1-5 are objected to since claims 1 and 2 recite non-elected SEQ ID NO:12. Claims 3-5 depend from claim 1.

4. Double Patenting

A. The rejection of claim 1-5 under the judicially created doctrine of obviousness-type double patenting has been withdrawn in view of Applicants' arguments that SEQ ID NO:1 and 4-11 are not described, nor suggested, in U.S. Patent 6,300,312.

5. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. The rejection of claims 1 and 3-5 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendment to claim 1 to remove the phrase "functional peptide analogs thereof."

B. Claims 1-5 are rejected under 35 USC 112, first paragraph because the specification, while being enabling for the peptides of SEQ ID NO:1 and 4-11, does not reasonably provide enablement for proteins which are "**at least 90% homologous**" to these SEQ ID NOs, nor does the specification provide enablement for "**preventing**" premature delivery of a fetus, or dysmenorrhea. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming all peptides which are at least about 90% homologous to SEQ ID NO:1 and 4-12 (Applicants are reminded that SEQ ID NO:12 is a non-elected SEQ ID NO). As seen in the below rejection under 35 USC 112, second paragraph, these peptides are only 8 amino acids in length. Making even one change in these peptides would produce a protein which is approximately 88% identical to SEQ ID NO:1 and 4-12. Therefore, Applicants have not provided any guidance or working examples of any peptides other than SEQ ID NO:1 and 4-12 which meet this limitation. Furthermore, even if this limitation was amended, Applicants provide limitation in claim 2 as to what the function of these peptides would be, such as, for example, "wherein said peptide is a prostaglandin-F2α receptor antagonist." It is not predictable to one of ordinary skill in the art how to make a functional peptide other than those of SEQ ID NO:1 and 4-11, especially since there is no limitation provided in the claim as to what this function would be. In addition, the way claim 2 reads, the first two amino acids, "I" and "L" of SEQ ID NO:1 and 4-12 can be altered. However, the absence of a functional limitation raises an enablement issue since none of the peptides Applicants have disclosed involve altering the first two amino acids, "I" and "L."

In addition, Applicants have only demonstrated in the specification that the antagonists, PCP-8 and PCP-10 are able to inhibit uterine contractions ex vivo. Applicants have not provided any evidence that these ex vivo results are indicative of successful prevention of premature delivery of a fetus in vivo,

or of preventing dysmenorrhea. These conditions are, respectfully, more complex than simply inhibiting uterine contractions (e.g. premature delivery), or do not even have to involve uterine contractions at all (e.g. dysmenorrhea) "Prevention" implies that 100% of a target population would be 100% free from any of the claimed disorders. In the absence of any supporting evidence, such as pointing out exactly where in the specification support for "preventing" these disorders is, or a Declaration under 37 CFR 1.132, stating that the disclosed ex vivo uterine contraction model is an art-accepted model for preventing the claimed conditions, Applicants, at most, would be enabled for "decreasing the likelihood" of these conditions. As of this Office Action, the Examiner was unable to find any prostaglandin antagonists which are able to prevent premature delivery of a fetus.

In summary, the breadth of the claims is excessive with regard to Applicants claiming all peptides which are at least about 90% identical to SEQ ID NO:1 or 4-12. There is also a lack of guidance and working examples of these peptides, including which residues are critical for protein function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make functional peptides of SEQ ID NO:1 and 4-11, as well as how these peptides which are effective in an ex vivo model can be used to prevent the claimed disorders, leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

6. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 1 and 3-5 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendment to claim 1 to amend the phrase "G protein-coupled antagonist."

B. Claim 2 is confusing since the metes and bounds of "at least about 90% homology" are not known. These peptides are 8 residues. Therefore, changing even one residue would result in a peptide which is only 88% identical to the claimed peptides. The metes and bounds of the term "about" are also unknown. It is not clear if an substitution of one amino acid is tolerable. The claim can be amended, for example, by removing the term "at least about 90% homologous" and adding, for example, **and without adding new matter**, "with the substitution of one amino acid." Furthermore, the claim is indefinite because it is not understood what is meant by the phrase "D-amino acid, an amino acid sequence." The Examiner believes that the term "or" should be placed before the word "an." However, this is not certain.

7. Claim Rejections - 35 USC § 102

A. The rejection of claim 1-5 under 35 USC 102 has been withdrawn in view of Applicants' arguments that SEQ ID NO:1 and 4-11 are not described, nor suggested, in U.S. Patent 6,300,312.

8. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
April 08, 2003

ROBERT LANDSMAN
PATENT EXAMINER